K014201

FEB 25 2002

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Trade Name:	Aaron Reusable Electrosurgical Electrode
Common Name:	Electrosurgical Electrode
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400)

Aaron Reusable Electrosurgical Electrodes are non-sterile, reusable electrosurgical electrodes are used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels during surgery.

The **Aaron Reusable Electrosurgical** is substantially equivalent to **Aaron Electrosurgical Electrodes** (K931338 and K942986) in operation, intended use, energy source, and method of preparation. Performance claims for the reusable electrodes differ from the predicate device in that they are not sold sterile and that they may be cleaned and resterilized by steam under pressure. **Aaron Reusable Electrosurgical Electrodes** in the loop configuration may be cleaned and sterilized up to 5 times. **Aaron Reusable Electrosurgical Electrodes** in the blade, needle, and ball configurations may be cleaned and sterilized up to 25 times. Cleaning and resterilization processes are validated in accordance with Good Hospital Practice: Steam Sterilization and Sterility Assurance (ANSI/AAMI ST46: 1993) and Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities: A Guide for Device Manufacturers (AAMI TIR 12: 1994). The validated cleaning and sterilization processes are provided in device labeling and instructions.

Testing performed on **Aaron Reusable Electrosurgical Electrodes** indicate that the devices are substantially equivalent in method of operation, safety, and performance.

In conclusion, **Aaron Reusable Electrosurgical Electrodes** substantially equivalent to predicate devices (Aaron Electrosurgical Electrodes) in methods of operation, intended use, and results derived from operation.

Submitted By: Richard Kozloff
Vice-President ; Quality Assurance
Aaron Medical Industries
7100 30th Avenue North
St. Petersburg, FL 33710

Contact Person: Richard Kozloff
Date: December 17, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2002

Mr. Richard Kozloff
Vice President, Quality Assurance
and Regulatory Affairs
Aaron Industries
7100 30th Avenue North
St. Petersburg, Florida 33710

Re: K014201
Trade/Device Name: Aaron Reusable Electrosurgical Electrodes
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AARON MEDICAL INDUSTRIES
AARON REUSABLE ELECTROSURGICAL ELECTRODE

510 (K) NOTIFICATION

INDICATIONS FOR USE

510(k) Number (if known): K014201

Device Name: Aaron Reusable Electrosurgical Electrodes

Indications for Use:

Aaron Reusable Electrosurgical Electrodes are non-sterile, reusable electrosurgical electrodes, used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014201

(Optional Format 3-10-98)